JC03 Rec'd PCT/PTO 2.1 SEP 2009

Approved for use through 3/31/2007. OMB 0651-0021 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL LETTER TO THE UNITED STATES ATTORNEY'S DOCKET NUMBER PC2041001 **DESIGNATED/ELECTED OFFICE (DO/EO/US)** CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED PCT/CA2004/000406 March 19, 2004 March 21, 2003 TITLE OF INVENTION Isopropanolate of Azithromycin and Method of Manufacturing APPLICANT(S) FOR DO/EO/US Tim Fat Tam, Khashayar Karamian, Shui Sheng Hu, Anna Chow and Richard William Storey Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: 1. X This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. X The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. X An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: 11. An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. X An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. X A preliminary amendment. 14. 🗀 An Application Data Sheet under 37 CFR 1.76. 15. A substitute specification. 16. X A power of attorney and/or change of address letter. 17. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. 18. L A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. L A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. Page 1 of 3

JC05 Rec'd PCT/PTO 21 SEP 2005

PTO-1390 (Rev. 07-2005)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| U.S. APPLICAT | ION NI (U) | 5 5011 | PCT/CA2004/ | | PT2041001 | (ET NUMBER |
|--|--|------------------|------------------------------|----------------|---------------------------------------|--------------|
| 20. Other | items or information | on: | | | · · · · · · · · · · · · · · · · · · · | |
| | | | | | | |
| The follo | owing fees have b | een submitted | | | CALCULATIONS | PTO USE ONLY |
| 21. X Basic national fee (37 CFR 1.492(a)) | | | | | \$ 300.00 | |
| 22. X Exam | nination fee (37 CF | R 1.492(c)) | | | | |
| by IPEA/ | ion prepared by IS US indicates all cl | \$ 200.00 | | | | |
| If the written opin IPEA/US Search fee (37 C International Sea previously | rch fee (37 CFR 1. ion of the ISA/US indicates all claim FR 1.445(a)(2)) had Searching Aurch Report prepare communicated to s | \$ 400.00 | | | | |
| | TOTAL OF 21, 22 | 900.00 | | | | |
| Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | | | Ž. | |
| Total Sheets | Extra Sheets Number of each additional 50 or fraction thereof (round up to a whole number) | | | | | |
| - 100 = | /50 = | | | × \$250 | \$ 0.00 | l |
| Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)). | | | | | \$ | |
| CLAIMS | NUMB | ER FILED | NUMBER EXTRA | RATE | \$ | |
| Total claims | | 20 - 20 = | 0 | × \$50 | \$ 0.00 | |
| Independent clair | ms | 6 -3= | 3 | × \$200 | \$ 600.00 | |
| MULTIPLE DEPE | ENDENT CLAIM(S | + \$360 | \$ 360.00 | | | |
| | | | | CALCULATIONS = | \$ 960.00 | |
| Applicant cla | ims small entity st | tatus. See 37 CF | R 1.27. Fees above are reduc | ed by 1/2. | | |
| | | | | SUBTOTAL = | \$ 1,860.00 | |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). | | | | | \$ | |
| TOTAL NATIONAL FEE = | | | | | \$ 1,860.00 | |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property + | | | | | \$ 40.00 | |
| TOTAL FEES ENCLOSED = | | | | | \$ 1,900.00 | |
| | | | | | Amount to be refunded: | \$ |
| | ···· | | | | Amount to be charged | \$ |

JC05 Rec'd PCT/PTO 21 SEP 2005

10/550104

PTO-1390 (Rev. 07-2005)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| a. X | A check in the amount of \$ 1,900.00 | to cover the above | e fees is enclosed. | | | | |
|--|---|--|--|--|--|--|--|
| b. 🗀 | Please charge my Deposit Account NoA duplicate copy of this sheet is enclosed. | _ in the amount of \$ _ | to cover the above fees. | | | | |
| c. X | The Commissioner is hereby authorized to charge any Account No. $\underline{08-3255}$. A duplicate copy of this st | y additional fees whic neet is enclosed. | h may be required, or credit any overpayment to Deposit | | | | |
| d. 🗌 | Fees are to be charged to a credit card. WARNING: In be included on this form. Provide credit card information. | nformation on this for ation and authorizatio | m may become public. Credit card information should not on PTO-2038. | | | | |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status. | | | | | | | |
| SEND A | LL CORRESPONDENCE TO: | | SIGNATURE SIGNATURE Kitt Sinden NAME 50,188 REGISTRATION NUMBER | | | | |
| | | | | | | | |
| à | | | | | | | |





Ivor M. Hughes

Barrister & Solicitor

Patent & Trade Mark Agents Canada, United States 10/550104

Ivor M. Hughes Rick Tuzi

Patent Agents Neil H. Hughes, P.Eng. Marcelo K. Sarkis, P.Eng. Wm. Kitt Sinden Samuel T. Tekie, P.Eng.

Our Ref: PC2041001

September 20, 2005

Via Courier

Director
United States Patent and Trademark Office
Customer Service Window, Mail Stop PCT
Randolph Building
401 Dulany Street
Alexandria, VA 22314
U.S.A.

Dear Sir/Madam:

Re:

National Phase Entry in United States

of Tim Fat Tam, Khashayar Karimian, Shui Sheng Hu, Anna Chow

and Richard William Storey

for Isopropanolate of Azithromycin and Method of

Manufacturing

based on International PCT Application No. PCT/CA2004/000406

International Filing Date: March 19, 2004

Due Date: September 21, 2005

Enclosed herewith please find the following documentation for filing with the Director in connection with the National Phase entry in the United States of PCT Application No. PCT/CA2004/000347 under 35 U.S.C. 371:

- (a) Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) concerning a submission under 35 U.S.C. 371 (Form PTO-1390) (3 sheets);
- (b) Copy of International Publication No. WO 2004/083227 A1 (22 sheets);
- (c) Declaration of the inventors (Tim Fat Tam, Khashayar Karimian, Shui Sheng Hu, Anna Chow and Richard William Storey) (2 sheets);
- (d) Notarial copy of Assignment and Recordation Form Cover Sheet, Form PTO-1595 (4 sheets);
- (e) Preliminary Amendment (9 sheets);



- (f) Powers of Attorney for each of Tim Fat Tam, Khashayar Karimian, Shui Sheng Hu and Anna Chow, as inventors (4 sheets); and
- (g) Power of Attorney for Bernard C. Sherman, as Chairman & C.E.O. of Apotex Inc. (1 sheet).

Enclosed with this material please find a cheque payable to the **Director of the United States Patent and Trademark Office** in the amount of **U.S. \$1,900.00**, comprising of the following:

| Description | | Fee |
|---|-----|-----------------|
| Basic filing fee | \$ | 300.00 |
| Examination fee | | 200.00 |
| Search fee | | 400.00 |
| 0 total claims over and above the twenty allowed per application | | 0.00 |
| 3 independent claims over and above the three allowed per application | | 600.00 |
| Multiple dependent claim fee | | 360.00 |
| Size fee for each additional 50 sheets that exceeds 100 sheets | | 0.00 |
| Recording an Assignment | _ | 40.00 |
| Total: | \$1 | <u>1,900.00</u> |

If there is any deficiency or surplusage of the fees enclosed for filing this Application, please obtain any such deficiency from or credit the surplusage to Deposit Account 08-3255 and advise Applicant's Agent.



Also enclosed herewith is a stamped, self-addressed verification card which we request that you kindly acknowledge and return to this office at the earliest opportunity. We thank the Director for his cooperation in this regard and look forward to receiving filing data in this matter.

Respectfully submitted,

Kitt Sinden

Registration No. 50,188 Agent for Applicant

/jf

Enclosures